

REMARKS

Introductory Comments:

Claims 28-31, 36-39 and 42-45 were examined in the Office Action under reply and rejected solely under 35 U.S.C. §112 second paragraph. These rejections are respectfully traversed as discussed more fully below.

Applicants note with appreciation the withdrawal of the previous rejections under 35 U.S.C. §112, second paragraph; 35 U.S.C. §102(b); and 35 U.S.C. §102(e); as well as the withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting.

Overview of the Above Amendments:

Claim 28 has been amended in order to recite the subject invention with greater particularity. Specifically, claim 28 has been amended to clarify the buffer and sample flow characteristics of the test strip, as requested by the Office. Support for the foregoing amendments can be found throughout the specification at, e.g., page 12, line 24 through page 13, line 2; and page 13, lines 14-17.

Amendment of claim 28 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the unamended claims.

Rejections Under 35 U.S.C. §112, Second Paragraph:

Claims 28-31, 36-39 and 42-45 were rejected under 35 U.S.C. §112, second paragraph as indefinite. The Office asserts claim 28 “is confusing with respect to the description of the terminal buffer zone.” Office Action, page 2. The Office queries how the terminal buffer flow zone causes the buffer to change direction.

As explained throughout the specification, such as at pages 12-13, bridging paragraph, and page 15, lines 12-17, buffer flows back towards the buffer addition zone by positioning an absorbent zone relative to the buffer addition zone such that when a predetermined volume of buffer is added to the test strip, the diffusion front of the buffer expands across the one or more test zones to a terminal buffer flow zone. When the buffer reaches the terminal buffer flow zone, the absorbent properties (e.g., capillary action) of the absorbent zone cause the buffer to be drawn backward across the test zones toward the buffer addition zone and ultimately into the absorbent zone. Applicants have amended claim 28 to clarify this process. Thus, this basis for rejection has been overcome.

The Office also asks with respect to claim 28 how the sample and buffer solution, added to two different ends of the test strip, are able to diffuse towards each other and not in one direction. Office Action, page 2. As explained throughout the specification and shown in the figures, when buffer is added to the test strip, it begins to diffuse in both directions, both proximally and distally across the test strip. The distal front of the buffer ultimately reaches the terminal buffer zone, and as explained above, capillary action by the absorbent zone then draws the buffer towards the absorbent zone (see, page 15, lines 12-17 and Figures 2A-2D and 3A-3D). When sample is added to the sample addition zone, it also diffuses towards the absorbent zone, and can also diffuse in the opposite direction (see, page 13, lines 14-18; pages 16-17, bridging paragraph; page 17, lines 26-27 and Figures 2E-2H and 3A-3H). Claim 28 has been amended to clarify that both the sample and the buffer diffuse towards the absorbent zone.

Finally, claims 43 and 44 were rejected as indefinite "because it is unclear where the control zones are located relative to the various test zones, buffer zones and sample zones." Office Action, page 2. However, claims 43 and 44 both recite that the control zone with a control binding agent immobilized therein is found within the test zone. Accordingly, the recitation of control zones is believed to be clear. Moreover, claims 43 and 44 were not rejected on this basis previously and could have been as the recitation of control zones was present in the claims as filed. Should the Examiner maintain this rejection, applicants submit that the finality of the present Office Action must be withdrawn. M.P.E.P. §706.07(a) makes clear that a rejection should not be made final "where the Examiner introduces a new ground of rejection not necessitated by amendment of the application by applicant." (Emphasis added). Accordingly, the Office cannot now, in the final action, state a new rejection which could have been asserted previously, without giving applicants an opportunity to address the same. Such is an abridgment of applicants' right to due process. Thus, applicants request withdrawal of the finality of the present Office Action should this rejection be maintained.


Based on the foregoing, the rejection of the claims under 35 U.S.C. §112, second paragraph is believed to be overcome and withdrawal thereof is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

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By: 
Roberta L. Robins
Registration No. 33,208
Attorney for Applicant

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Telephone: (650) 493-3400
Fax: (650) 493-3440